DOCKET NO.: TJU-1156
PATENT APPLICATION

SERIAL NO.: 08/203,004
FILED: FEBRUARY 28, 1994

Please amend the claim 3 as follows:

Claim 3, line 1, following "claim", delete "1", insert therefor --32--.

Please rewrite claim 22 as follows:

Claim 22 (Twice Amended). A pharmaceutical composition comprising tumor cell extracts comprising a peptide or a mixture of tumor cells and tumor cell extracts comprising a peptide, wherein said tumor cell extracts comprising a peptide or said mixture of tumor cells and tumor cell extracts comprising a peptide is conjugated to a hapten, said composition mixed with an immunological adjuvant, said composition useful for the treatment of melanoma.

REMARKS

Claims 1-7 and 10-31 are pending in the above-identified application. Claims 32 and 33 are newly added; claims 3 and 22 are amended above. Support for newly added claims 32 and 33 may be found in the specification as filed, see for example original claims 1 and 22, respectively.

Claims 32 and 33 are in compliance with the requirements of §112, first paragraph, as the specification adequately teaches how to make and use the invention. In the Official Action dated

April 7, 1995, it was asserted that the specification failed to teach how to make and use the invention with respect to claims directed at the treatment of cancer including melanoma, lung cancer, colon cancer, breast cancer, kidney cancer and prostate cancer. The Official Action acknowledged Applicant's clinical data for the treatment of melanoma. The Official Action cited reference Bystryn to support the assertion that the treatment of cancer using tumor antigens is unpredictable. The Official Action cited reference Hellstrom to support the assertion that the treatment of cancer using allogenic tumor antigens is unpredictable. Applicant respectfully requests reconsideration. Applicant respectfully urges that when viewed as a whole, the evidence of record supports a finding that the claimed invention is operable and that the requirements of 35 USC §112, first paragraph have been met.

Applicant respectfully asserts that the data in the specification is sufficient to demonstrate patentable utility and compliance with the requirements of 35 USC §112, first paragraph. The subject matter claimed in the present application has practical utility in currently available form. Those having ordinary skill in the art would accept Applicant's data presented therein as sufficient to establish that Applicant has taught how to make and use the invention. The claimed method would be *prima facie* believable to those having ordinary skill in the art.

The reasoning and evidence of record clearly support the asserted utility. In view of the totality of the evidence under consideration, one having ordinary skill in the art would conclude that it is more likely than not that the assertion of operability of the claimed invention is true. The assertion is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided. There is no flaw in the logic underlying the assertion, and the facts upon which the assertion is based are consistent with the logic underlying the assertion. The data in the specification provides sufficient evidence that there is a reasonable expectation of success of the invention as claimed. One having ordinary skill in the art, viewing all of the evidence of record, would conclude that the asserted utility is credible and that the utility requirements for the claimed invention have been met.

The Court of Appeals for the Federal Circuit again recently decided the issue of what the applicant must "prove regarding the practical utility or usefulness of the invention for which patent protection is sought" in the context of a 112, first paragraph rejection. *In re Brana*, 1995 U.S. App. LEXIS 6362 (C.A.F.C. 1995). Applicant notes that the requirements under the law for obtaining a patent are not to be confused with the

requirements for obtaining government approval to market a particular drug for human use. *Id.* at *21.

> Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Id. at *24. Further, as the present invention is not directed to the treatment of cancer, Applicant's burden should be comparable to the methods of the present invention; *i.e.* the burden should not be incredible.

There is no requirement for proof of utility, unless said utility is unbelievable on its face. *In re Isaacs and Lindenmann*, 146 U.S.P.Q. 193 (C.C.P.A. 1965). The disclosure that a compound exhibits some pharmacological property is sufficient to satisfy utility requirements for this compound under the statute. See *In re Krimmel*, 130 U.S.P.Q. 215 (C.C.P.A. 1961), *In re Bergel*, 130 U.S.P.Q. 206 (C.C.P.A. 1961), and *In re Dodson* 130 U.S.P.Q. 224 (C.C.P.A. 1961). There is no requirement that one must demonstrate that a compound having pharmaceutical utility must be operable in humans for the therapy disclosed.

> The Examiner's attention is directed to *In re Langer*, 503 F.2d 1380....especially at 297 (CCPA 1974). The Court there held: '...a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of §101 unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope'. No reason to doubt 'the objective truth' of the asserted utility having been advanced by the Examiner, we accept appellant's disclosure of utility corresponding in scope to the claimed subject matter.

Ex parte Rubin, 5 U.S.P.Q.2d 1461, 1462 (B.P.A.I. 1987).

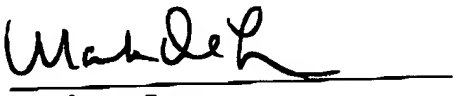
As evidenced by Applicant's original disclosure, and further supported by the Declaration under 37 C.F.R. §1.132 of Applicant Dr. Bruce A. Lessey, the present invention demonstrates utility and an adequate written description. Dr. Lessey provides a mouse model to demonstrate utility of the invention and the role of integrins in implantation. The mouse model is an excellent example to teach utility of the present invention due to the similarities between the mouse and human systems.

Applicant has met the burden provided by M.P.E.P. §608.01(p), the Board of Patent Appeals and Interferences, and the Court of Appeals for the Federal Circuit in establishing the enablement and written description requirement of the present invention. In view of the remarks set forth above Applicant has met the burden of proof required to establish enablement and

written description of the present invention and the burden has now shifted to the Examiner. Accordingly, Applicant respectfully requests withdrawal of the objection and rejection under 35 U.S.C. §112, first paragraph.

In view of the foregoing, Applicant respectfully requests reconsideration and allowance of claims 1-7, 10-31, and new claims 32 and 33. Early and favorable notification to that effect is earnestly solicited.

Respectfully submitted,



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